Abstract- Scientific - A **PILOT** STUDY OF SEQUENTIAL VACCINATIONS WITH RECOMBINANT VACCINIA-CEA(6D)-TRICOM, AND RECOMBINANT FOWLPOX-CEA(6D)-TRICOM (B7.1/ICAM-l/LFA-3) WITH SARGRAMOSTIM (GM-CSF), IN CONJUNCTION WITH STANDARD ADJUVANT CHEMOTHERAPY IN HIGH RISK BREAST CANCER PATIENTS STATUS POST SURGERY WITH 4+ OR MORE LYMPH NODES AND CEA EXPRESSING TUMORS.

Four cycles of doxorubicin and cyclophosphamide (AC) followed by 4 cycles of paclitaxel (T) has been approved by the FDA as a treatment regimen for patients with node-positive breast cancer in the United States. Despite these recent advances in adjuvant chemotherapy for breast cancer patients with 4+ node, the relapse rate is still significant. **According to a study published in the New England Journal of Medicine, despite adjuvant chemotherapy in this population, the overall survival at 5 years is 39% and drops to 24% at 10 years.** (52) Thus, novel approaches combining chemotherapy with vaccines may provide an additional benefit to these patients with minimal additional toxicity. This trial will evaluate the immunologic effects of two vaccine arms priming with recombinant vaccinia virus that expresses the gene for the tumor associated antigen (TAA) CEA the gene for 3 costimulatory molecules B7.1, ICAM and LFA-3(TRICOM)[rV-CEA/TRICOM] followed by sequential vaccinations with recombinant fowlpox virus containing the CEA gene and TRICOM (rF-CEA/Tricom). In arm A patients will receive vaccinations before and after as well as during the administration of an FDA approved chemotherapy regimen for adjuvant therapy in node positive breast cancer. Patients randomized to arm B will receive the vaccinations before and after chemotherapy, but not during the chemotherapy treatment. HLA-A2 patients with a PS level of 0-1 with CEA positive adenocarcinomas of the breast undergoing adjuvant chemotherapy following surgery with Stage 2 or 3 breast ca. with 4 or more + axillary lymph nodes will be eligible for the vaccine. The chemotherapy proposed in this study is a standard regimen and may be administered to the patient by a local oncologist or at the NIH Clinical Center. Patients may begin treatment 2-3 weeks post surgery. All vaccinations and blood draws for immunologic monitoring will be performed at the NIH Clinical Center on weeks 0 (day 1),2,5,8,11,14,17,20,23,26,30,38,50, and 54. Patients will be followed for DFS (disease free survival) every 6 months after completion of the protocol until disease progression or for a total of 5 years at the NIH Clinical Center. Patients should continue follow up visits with their local oncologist on a 6-month basis.